DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 19, 2015

Vivonic GmbH
Andreas Hessberger
Manager Regulatory Affairs
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Germany

Re: K143617
Trade/Device Name: AquaC UNO H
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: September 9,2015
Received: September 9, 2015

Dear Andreas Hessberger,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143617

Device Name
AquaC UNO H

Indications for Use *(Describe)*
The AquaC UNO H Portable Water Purification System is a reverse osmosis unit intended for use with hemodialysis systems to remove organic and inorganic substances and microbial contaminants from the water used for treating hemodialysis patients or related therapies.
The AquaC UNO H can be connected to hemodialysis equipment used in hospitals, clinics and in home environments. This device is intended to be a component in a complete water purification system, and is not a complete water treatment system. The reverse osmosis unit must be preceded by pre-treatment devices, and may need to be followed by post-treatment devices as well, to meet current AAMI/ANSI and FDA recognized U.S. standards.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

As required by section 807.92(c)

AquaC UNO H
Water Purification System

Contact Information

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Date: 2014-12-17

Device Identification

Trade Name:	**AquaC UNO H**
Common Name:	Water Purification System
Classification Name:	Subsystem, water purification
Product Code:	FIP
Device Class:	II
Classification Reg.:	876.5665

Claiming substantial equivalence to

K110578 Mar Cor Millenium HX
K093608 Mar Cor WRO 300 H

Device Description

The AquaC UNO H Water Purification System is a microcontroller-controlled, fully automatic reverse osmosis system with heat disinfection function which uses pretreated soft water for the production of highly deionized water, also called permeate.

The intended use of the reverse osmosis device is to remove organic and inorganic ions and microbiological contaminants from the feed water to fulfill the requirements of ISO 13959 'water for haemodialysis and related therapies'.
The feed water must be of drinking water standard, filtered, free of iron, softened and free of chlorine. Potentially critical limits must be monitored by regular checks.
Bacterial growth in the system must be prevented by continuous operation of the system with a minimum of idle times and by preventive measures such as chemical or heat disinfection.

The device consists of a water inlet section where the inflowing volume of water is volumetrically measured. The water is stored in a break tank and is used by the pump to generate high pressure. The pump generates the high pressure and transports the water to the membrane.
The permeate flows from the membrane through the conductivity cell to the permeate outlet into the ring main. The ring main can be connected directly to a dialysis machine.

The concentrate is discarded via the drain valve to the drain.

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Commercial Register: AG Aschaffenburg / HRB 7445
VAT ID: DE 812 809 157

Certified according DIN EN ISO 9001:2008
and DIN EN ISO 13485:2007

Materials used

Polypropylene (PP)
Stainless steel
Silicone
Polysulfone (PSU)
Fluorinated ethylene propylene (FEP)
Ethylene propylene diene monomer (EPDM)
Polyamide (PA)
Polyvinylidene fluoride (PVDF)
Noryl GTX
Titan
Ceramics

Indication for Use

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Comparison to Predicate Devices

The AquaC UNO H Water Purification System is substantially equivalent to many other marketed devices that are used in heamodialysis. This includes the Predicate Devices *Mar Cor Millenium HX* and *Mar Cor WRO 300 H*.

All systems utilize pretreated potable water and a reverse osmosis with a polyamide thin-film composite membrane for the purification of water
All systems have the same intended use and they are located in hospitals, dialysis centers or home environment.
All system uses chemicals and hot water for disinfection.

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Summary of Non-Clinical Performance Data

As non-clinical tests the following tests has been performed on the AquaC UNO H Water Purification System:
- Software validation (according IEC 62304)
- Chemical and microbiological testing (according ISO 13959, ISO 23500)
- Biocompatibility testing (according ISO 10993)
- Electrical and electro-magnetically safety testing (according IEC 60601-1,IEC 606001-1-2)
- Usability testing (according IEC 60601-1-6)
- Performance testing (according to the specifications of the device)

The tests have been performed by internal and external testing laboratories. These tests demonstrate the compliance to the following standards:
- ISO 23500 First edition 2011-05-15
- ISO 11663 First edition 2009-04-15
- ISO 13959 Second edition 2009-04-15
- IEC 60601-1:2005
- IEC 60601-1-2:2007
- IEC 60601-1-6:2010
- IEC 60601-1-11:2010
- IEC 62304:2006
- ISO 10993:2009
- ISO 14971:2007, Corrected version 2007-10-01
- ISO 26722 First edition 2009-04-15

In addition each system will be tested according internal inspection requests that contain functional, safety and performance testing as well as the configuration of the devices.

The results of all these tests show that all specifications and requirements have been met and the AquaC UNO H water purification system is substantially equivalent to the predicate devices.

Conclusion

The AquaC UNO H Water Purification System is capable to meet relevant standards and specifications for the use in haemodialysis and related therapies. The information and performance data provided indicates that the AquaC UNO H is safe and effective and performs at least as well as the predicate devices when used in accordance to the instruction of use.

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